REMARKS

Claims 1-6, 8-22 and 24 are pending in the subject application. Claims 1, 14, 19, and 24 are amended and claims 25-29 are added. Applicants submit that the amendments herein introduce no new matter, support therefore being found throughout the application and drawings as originally filed.

Applicants request reconsideration based on the amendments and the following remarks.

1. 35 U.S.C. §112 Rejections

Claims 19-22 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office asserts that the phrase "or such that" makes it unclear whether the limitations following the phrase are part of the claimed invention.

Without agreeing with the rejection, Applicants amended claim 19 for further clarification. Claim 19 reads that "the reservoir is disposed exterior the eye on the sclera or within the eye". It is respectfully submitted that this language is not indefinite or unclear. For example, as set out in MPEP §2173.05(h), "alternate expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims". In this case, it is clear that the claim is directed to an embodiment where the reservoir is either positioned (a) exterior the eye on the sclera or (b) within the eye. Such alternate claim language provides clear guidance as to what is encompassed by the claim.

Reconsideration and withdrawal of the rejection is respectfully requested.

1. 35 U.S.C. §102 Rejections

Claim 1 is rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,725,493 to Avery et al. (hereinafter "Avery"). Applicants respectfully traverse.

Applicants recite, in amended claim 1, a subretinal delivery device comprising a reservoir, a cannula extending from the reservoir, and a securing mechanism near the distal end of the cannula. As set out, the cannula has a length and is configured such that it extends from the reservoir through the vitreous and through the retina with a distal end terminating in a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. As further set out, the securing mechanism is configured to secure a distal portion of the cannula to the retina. As further set out, the cannula is configured so that an agent in the reservoir is released from the reservoir through the cannula to the eye subretinally.

Avery at least does not teach or suggest (1) a securing mechanism near the distal end of the cannula, the securing mechanism configured to secure a distal portion of the cannula to the retina or (2) a cannula having a length and configured so that it extends from the reservoir through the vitreous and through the retina with a distal end terminating in a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye.

Avery describes an intravitreal medicine delivery device as shown below:

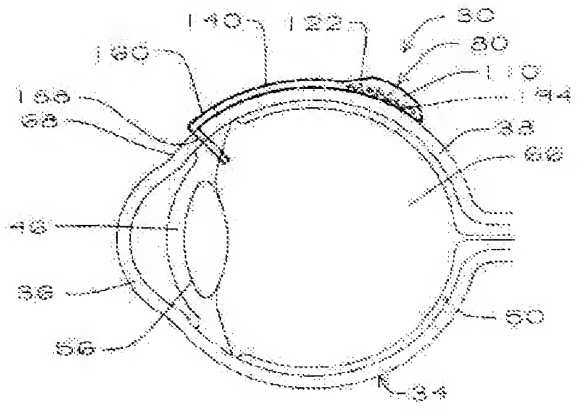

Fig. 2

According to Avery, the housing 80 is designed for positioning on the outer surface of the eyeball (see, e.g. col. 4, lines 52-65), and a preformed delivery tube 140 extends therefrom having sufficient rigidity to maintain a longitudinal curvature along the outer surface of the eyeball (as shown in Figs. 5-6) (see, e.g. col. 6, lines 28-33). A semi-rigid tubular elbow 160 extends from the end of tube 140 and at an angle (e.g. 80-90°) downwards to terminate in the vitreous (see, e.g. col. 6, lines 34-40; Figs. 2-6). As set out, "the rigidity of the elbow allows the position of the intravitreal extension to be controlled as it is inserted into the cavity" (col. 7, lines 5-9) and the "rigidity of the elbow and its attachment to the sclera (FIGS. 1 and 2) maintain the intravitreal extension of the implant tube in the position in which it is initially placed so that it does not move around in the cavity as the implant is worn and used by the patient." (Col. 7, lines 18-22)

Clearly, the structure of Avery's delivery tube 140, tubular elbow 160, and extension 164 are not of a length or configures to extends from the housing 80 through the vitreous and through the retina with a distal end terminating in a subretinal space. Avery's rigid preformed delivery tube is specifically designed to extend from the housing

along the curvature of the outer eye surface and angle downwards at the semi rigid tubular elbow 160 into the eye to terminate in the vitreous.

Further, Avery does not teach or suggest a securing mechanism near the distal end of the cannula nor would there be any teaching or suggestion to modify Avery to provide such a securing mechanism. Avery's pre-formed rigid tube 140 and elbow provide the end of Avery's device positioned at a desired location within the vitreous. The vitreous is a viscous fluid and, thus, even if there was a securing mechanism provided at the distal end of the device, it would not serve any purpose is securing the distal portion of the device within the viscous vitreous fluid.

In view of the above, it is respectfully submitted that claim 1 is clearly not anticipated by Avery. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §103 Rejections

Claims 2-6, 8-22 and 24 are rejected under 35 U.S.C. §103(a) over Avery and U.S. Patent No. 5,454,796 to Krupin (hereinafter "Krupin") or U.S. Patent No. 5,370,607 to Memmen (hereinafter "Memmen"). Applicants respectfully traverse.

As set forth above, claim 1 is not taught or suggested by Avery.

Krupin is cited for allegedly describing a ring-shaped delivery device. However, this does not remedy the above-noted deficiencies in Avery. Krupin is directed towards a device that treats glaucoma by draining fluid out of the anterior chamber of the eye. As such, Krupin describes a plate 16 that is designed for positioning on the outer surface of the eye in one of four quadrants between two rectus muscles (e.g. 50, 52 as shown in Fig. 5). A tube 14 is configured to extend from the plate across the surface of the eye and terminate in the anterior chamber 42. Clearly, Krupin's tube 14 is not configured for nor is it of a length to extend from the housing 80 through the vitreous

and through the retina with a distal end terminating in a subretinal space. Further Krupin does not teach or suggest a securing mechanism near the distal end of the tube 14 nor is there any teaching or suggestion to modify Krupin to provide such a securing mechanism – rather, this teaching comes purely from Applicants' disclosure.

Like Krupin, Memmen also does not remedy the above-noted deficiencies in Avery. Krupin describes a device and method for treating glaucoma by draining fluid out of the anterior chamber of the eye. As such, Memmen's device includes a reservoir 20 configured so as to be positioned in the same way as Krupin with a drainage tube 60 configured to extend from the reservoir 20 into the anterior chamber of the eye. Clearly, Memmen's tube 60 is not configured for nor is it of a length to extend from the reservoir 20 through the vitreous and through the retina with a distal end terminating in a subretinal space. Further Memmen does not teach or suggest a securing mechanism near the distal end of the tube 60 nor is there any teaching or suggestion to modify Memmen to provide such a securing mechanism – rather, this teaching comes purely from Applicants' disclosure.

Thus, clearly no combination of Avery, Krupin, and Memmen would provide Applicants' subretinal delivery device and methods of treatment as set out in claim 1. Claims 2-6, 8-18, and 25-26 depend from claim 1 and, thus, also are patentable over Avery, Krupin, and Memmen. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants further recite, in amended claim 24, a subretinal delivery device comprising a reservoir and a cannula extending from the reservoir. As set out, the cannula has a length and is configured to extend from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. Further, the cannula has a pointed distal end for insertion through the retina. Still further, the distal end and at least a distal portion of the cannula has a cross-sectional size that allows for

disposal and retainment within the subretinal space between the retina and choroid of the eye.

As set forth above with respect to claim 1, clearly no combination of Avery, Krupin, and Memmen would provide Applicants' subretinal delivery device which is provided with a cannula having a length and configured so that it extends from the reservoir through the vitreous and through the retina with a distal end terminating in a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye.

Further, it is submitted that Avery, which describes a sleeve 162 (the portion of the device that extends into the eye and terminates in the vitreous) having a size of 19-20 gauge (approximately 0.81-0.92 mm) is not suitably sized for insertion and retainment in the subretinal space. In addition, Avery is not at all directed towards delivery of a material subretinally so there is absolutely no teaching to suggestion to modify Avery's device (in view of any teaching of Krupin, Memmen, or otherwise) such that it is suitably sized for insertion and retainment in the subretinal space.

Thus, it is respectfully submitted that claim 24 is patentable over Avery, Krupin, and Memmen. Reconsideration and withdrawal of the rejection is respectfully requested.

3. Allowable Claims

Applicants appreciate the discussion with Examiner Mendez on July 27, 2009 during which the status of claims 19-22 was discussed. Applicants understand that claims 19-22 are currently rejected in view of the 35 U.S.C. §112 rejections only and, upon overcoming the §112 rejections, will be allowable. As such, Applicants believe that currently amended claims 19-22 and further dependent claims 27-28 are allowable.

CONCLUSION

In view of the forgoing, Applicants believe the pending application is in condition for allowance. Early and favorable action is requested.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Dated: August 11, 2009

Respectfully submitted,

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